In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

JOSEPHINE INYANG,	*	
	*	No. 20-57V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	
	*	Filed: August 8, 2024
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for petitioner;
Debra A. Filteau-Begley, United States Dep't of Justice, Washington, DC, for respondent.

Finding of Fact[1]

Josephine Inyang alleges that an influenza vaccine, which was administered to her on November 21, 2017, caused her to suffer a neurologic problem known as neuromyelitis optica spectrum disorder ("NMOSD").[2] The Secretary disputes this

[1] Because this Finding of Fact contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Finding of Fact will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

[2] "Neuromyeltis optica spectrum disorder" or "NMOSD" includes the condition "neuromyelitis optica" or "NMO." See Exhibit C-1 (Bruna Garbui Dutra et al., "Neuromyelitis Optica Spectrum Disorders: Spectrum of MR Imaging Findings and Their Differential

allegation on several grounds, including an argument that Ms. Inyang suffered from an undiagnosed NMOSD before she received the vaccination.

I. Procedural History

Ms. Inyang started this case by filing her petition on January 17, 2020. She submitted various medical records, which included reports about MRIs. The Secretary denied that Ms. Inyang was entitled to compensation. Resp't's Rep., filed Dec. 4, 2020.

After multiple enlargements of time, Ms. Inyang supported her claim with a report from Lawrence Steinman, a neurologist who has frequently assisted petitioners seeking compensation in the Vaccine Program. Exhibit 18. Dr. Steinman opined that Ms. Inyang suffered from NMO and the flu vaccination caused it. Citing the National Institute of Neurological Disorders and Stroke website, Dr. Steinman described NMO as an autoimmune disease of the central nervous system predominantly affecting the optic nerves and spinal cord. Id. at 12. He explained that NMO develops when the immune system attacks healthy cells and proteins, most often in the spinal cord and eyes. Abnormal autoantibodies bind to the protein aquaporin-4, which activates other components of the immune system, resulting in inflammation and cell damage. Id. at 13. Those with NMO develop optic neuritis and transverse myelitis. Id. at 12. As part of this opinion, Dr. Steinman asserted that the onset of Ms. Inyang's NMO was "somewhere between Dec. 1 and Dec. 4." Id. at 33. Dr. Steinman did not specify in this section of his report what evidence supported his opinion regarding this onset. See id.

The Secretary opposed Dr. Steinman's opinion with an opinion from Michael Wilson, who is also a neurologist. Exhibit A. Although Dr. Wilson agreed with the diagnosis of NMOSD, Dr. Wilson disagreed with other parts of Dr. Steinman's report. Dr. Wilson maintained that Ms. Inyang was suffering from NMOSD *before* she was vaccinated for two reasons. First, Ms. Inyang reported severe headaches on the date of vaccination. Exhibit A at 7-8, citing Exhibit 2 at 82. Second, the MRIs that Ms. Inyang had shortly after the vaccination revealed non-enhanced lesions, meaning the lesions were "present before her vaccination." Id. at 8.

Diagnosis," 38(1) Radiographis 169 (2018)) at 3. The experts and the parties appear to use NMOSD and NMO interchangeably.

In the ensuing status conference, the parties discussed when Ms. Inyang developed NMOSD. She proposed obtaining the actual images of her MRIs and asking someone to review them. Ms. Inyang was uncertain as to whether she would ask Dr. Steinman to review the MRI images.

After Ms. Inyang obtained images from most MRIs and after multiple enlargements of time, she presented a report from a neuroradiologist, David Wilson. Dr. Wilson agreed that the MRIs from December 2017 showed that Ms. Inyang suffered from NMOSD at that time. Exhibit 45. However, he contended that the images did not confirm the presence of a demyelinating condition before the vaccination. Dr. Wilson proposed that in 2017, Ms. Inyang suffered from a different condition, cerebral small vessel disease ("cSVC"). Id. at 3. He described cSVC as "the narrowing and/or obstruction of small vessels in the brain causing hemorrhages, and a characteristic distribution of white matter abnormalities." Id.

In response to an opinion from a neuroradiologist, the Secretary retained another neuroradiologist, William B. Zucconi. Dr. Zucconi stated that the presence of non-enhancing lesions on the December 6, 2017 MRI meant that the lesions pre-dated the November 21, 2017 vaccination. Exhibit A at 8-9. Dr. Zucconi further opined that the lesions detected in the December 2017 MRIs were consistent with NMOSD.

The parties were asked whether they wanted to proceed to a hearing. Order, issued Jan. 4, 2024. They decided to proceed to a hearing during which only the neuroradiologists would testify. During the January 17, 2024 status conference, Ms. Inyang also stated that she received more MRI images and was attempting to obtain another MRI image. Accordingly, she was given 60 days to submit a report from Dr. Wilson. Order, issued Jan. 19, 2024.

After 60 days had passed, Ms. Inyang requested additional time. However, she did not establish good cause for enlarging the deadline. Order, issued Mar. 20, 2024.

The Secretary's expert, Dr. Zucconi, reviewed the images from the more recently obtained MRIs. He disclosed his opinion about their significance. Exhibit E.

A hearing was held on August 2, 2024, during which Dr. David Wilson[3] and Dr. Zucconi appeared in person. (The undersigned appreciates the experts' willingness to travel.) Both Dr. Wilson and Dr. Zucconi have testified in the Vaccine Program relatively infrequently. Despite (or because of) this inexperience, both Dr. Wilson and Dr. Zucconi made favorable impressions. Each presented their opinions respectfully and noted that he often agreed with his counterpart. Dr. Wilson and Dr. Zucconi acknowledged the limits of their knowledge. This humbleness enhanced the credibility of both witnesses.[4]

II. Events in Ms. Inyang's Life[5]

A. Before Vaccination and Vaccination

Ms. Inyang was born in 1961 in Cameroon. Exhibit 3 at 901, 903, Exhibit 12 (affidavit) ¶ 1. She worked as a social worker in that country as well as in the United States. She had stopped working as a social worker by the time of the allegedly causal vaccination. Exhibit 2 at 83-86. Although not employed, Ms. Inyang volunteered for church. Exhibit 12 at ¶ 2.

In 2010, Ms. Inyang underwent an MRI without contrast, although the reason for the MRI is not abundantly clear. Regardless, during the litigation, Ms. Inyang obtained the MRI images from 2010. According to Dr. Zucconi, the May 7, 2010 MRI shows "abnormal white matter signal hyperintensity in the deep and periatrial regions of the posterior cerebral hemispheres, in the same anatomic

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[3] Unless otherwise specified, all further references to "Dr. Wilson" refer to neuroradiologist Dr. David Wilson, not neurologist Dr. Michael Wilson.

[4] In accordance with the Federal Circuit stated that special masters should not make credibility assessments to determine the strength of an expert's testimony, Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009), the undersigned does not determine that Dr. Wilson or Dr. Zucconi were more credible based upon their demeanors. Nevertheless, the undersigned commends the trial presentation of the Secretary's attorney for carefully showing how Dr. Zucconi derived his opinions from MRI images presented on direct examination.

[5] Due to the agreement about the diagnosis of NMOSD, Ms. Inyang's medical history is summarized. Although this finding does not memorialize all the details, the medical records have been reviewed. Information about Ms. Inyang's medical history is summarized in the Amended Petition, filed Mar. 21, 2024, and Respondent's Report at 6-8. See also Exhibit 18 (Dr. Steinman's report) at 8-12; Exhibit A (Dr. Michael Wilson's report) at 3-4.

location demonstrated to undergo demyelination at future time points." Exhibit E at 1.

Other potentially relevant medical history includes a history of hypertension, obesity, and prediabetes. Exhibit 2 at 5-6, 83-84. Both Dr. Wilson and Dr. Zucconi testified that these traits predisposed Ms. Inyang to developing a small vessel disease.

Ms. Inyang sought care from her primary care physician, Michael Reiner, on November 21, 2017. She related that over the past two weeks, she has had "a fleeting kind of discomfort which occurs in her left frontal region, thinking that might be associated with a lot of reading that she does." Exhibit 2 at 82. Dr. Reiner assessed her as having "tension type headache, probably related to eye strain." Id. at 86. Dr. Reiner also gave her the flu vaccine.

B. Within One Month of the Vaccination

Ms. Inyang returned to Dr. Reiner's office ten days later. She reported "back pain after twisting, carrying groceries in the house." Exhibit 2 at 94 (Dec. 1, 2017). Dr. Reiner assessed her with a lumbosacral neuromuscular strain. Id. at 98.

Ms. Inyang saw Dr. Reiner again on December 4, 2017. She stated that on December 1, 2017, she had developed numbness extending down from her waist. The numbness had not extended to her chest. Exhibit 2 at 106. Dr. Reiner was concerned that she was suffering from a spinal cord stroke, transverse myelitis, or Guillain-Barré syndrome. He referred her to a neurologist and possible admission to the hospital. Id. at 110.

Later the same day, Ms. Inyang sought care in an emergency room. She recounted her history of numbness and pain, which had started in her left leg and now was present in both legs. Exhibit 3 at 1223. Ms. Inyang underwent MRIs of her spine, which revealed a lesion from C3 to T9. Id. at 1309-11. She was assessed with transverse myelitis and admitted to the hospital. Id. at 1226.

A neurologist, Irfan Altafullah, ordered additional testing. A test for an aquaporin 4 ("AQP4") antibody was positive. Exhibit 3 at 1296. The presence of an AQP4 antibody means that the person is likely to suffer from NMOSD. Exhibit 18 (Dr. Steinman) at 12; Exhibit A (Dr. Michael Wilson) at 4.

Ms. Inyang underwent a brain MRI on December 6, 2017. The radiologist who interpreted this imaging in 2017, Brian Larkin, identified chronic lacunar

infarcts. Exhibit 3 at 1305. As Dr. Zucconi explained at the hearing, an infarct is a lesion due to impaired flow of oxygen. See also Dorland's Illustrated Medical Dictionary at 934 (32nd ed. 2012)

As discussed extensively below, the neuroradiologists the parties retained also interpreted this imaging. Dr. Wilson and Dr. Zucconi agreed that the lesions were chronic. Exhibit 45 at 3; Exhibit C at 7. However, they disputed whether the chronic lesions were evidence of demyelination.

Following administration of high dose steroids, Ms. Inyang improved. She was discharged from the hospital on December 7, 2017 to inpatient rehabilitation. Exhibit 3 at 1270. Her discharge diagnosis was neuromyelitis optica.

During inpatient rehabilitation, Ms. Inyang improved but then developed memory and cognitive processing issues. Exhibit 3 at 939-40. This decline led to more investigation, including another brain MRI, which was performed on December 18, 2017. Exhibit 3 at 822. Again, Dr. Wilson and Dr. Zucconi reviewed this imaging and, again, had some agreements and some disagreements as discussed below.

Ms. Inyang ultimately was discharged home on December 21, 2017. Exhibit 3 at 819. Her diagnosis was NMO.

C. Treatment and Imaging Starting in 2018

Since her diagnosis, Ms. Inyang has continued to suffer from NMOSD. See Exhibit 12 (affidavit) ¶ 12. The ebbs and flows of her disease course generally do not contribute to determining when Ms. Inyang started suffering from NMOSD as the parties are relying upon neuroradiologists, who have based their opinions on successive MRIs that are discussed below.

Date	Location	Cite	Interpretation
2/4/2018	Cervical spine	5 at 54; 16 at 112	marked improvement
4/20/2018	Lumbar spine	3 at 442	marked improvement
4/20/2018	Thoracic spine	3 at 442	marked improvement

In October 2018, Ms. Inyang sought a second opinion from doctors at the Mayo Clinic, where she was seen by a neuroimmunologist, Oliver Tobin. Exhibit 7 at 7. In considering an appropriate medication for Ms. Inyang's pain, Dr. Tobin ordered additional MRIs. Id. at 10.

This set of MRIs on her brain and spine was performed on October 31, 2018 and "did not indicate any new lesions." Id. at 10. In this context, a neuroradiologist at Mayo Clinic, Dr. Erickson, compared the recent set of MRIs to the previous MRIs. Dr. Erickson interpreted the December 2017 MRIs as showing lesions "along the right lateral ventricle [that] have the more typical Dawson's finger appearance and would be consistent with demyelinating disease, and by report she has NMO. Abnormal T2 signal areas consistent with chronic demyelinating disease."

The retained experts disputed the Mayo Clinic's interpretation of the December 2017 MRIs. Dr. Zucconi agreed that Ms. Inyang's MRI's showed a "Dawson's finger." Exhibit C at 6. However, Dr. Wilson disagreed, maintaining that the December 2017 MRIs are "weak evidence of demyelinating injury in a patient with clear sCVD." Exhibit 45 at 7.[6]

Ms. Inyang underwent additional MRIs:

Date	Location	Cite	Interpretation
9/16/2020	Cervical spine	16 at 22	"No cervical cord abnormality. No atrophy or abnormal enhancement." "Mild cervical disc degeneration. Right-sided facet arthropathy at C3-4. No significant narrowing of the spinal canal or neural foramina./'

[6] The original pair of retained experts contribute relatively little to evaluating the Mayo Clinic's reinterpretation of the December 2017 MRIs. Dr. Steinman noted the MRIs from October 2018, but Dr. Steinman did not discuss the commentary about Dawson's fingers and demyelination. Exhibit 18 at 12. Dr. Michael Wilson, who did not have the MRIs imaging available for review, credited the Mayo Clinic's reinterpretation. Exhibit A at 4.

Date	Location	Cite	Interpretation
9/16/2020	Thoracic spine	16 at 24	"Intramedullary signal abnormality along the upper thoracic spinal cord, not apparently changed since October 2018. This is compatible with inflammatory myelitis. No new level of involvement, cord atrophy, or abnormal enhancement."
12/20/2020	Cervical spine	14 at 66, 69, 72	acute disease
12/20/2020	Thoracic spine	14 at 66, 69, 72	acute disease
12/20/2020	Brain	14 at 66, 69, 72	"Increase in the deep white matter T2 hyperintense lesions near the atria of both lateral ventricles since the 2017 MRI. Partial enhancement of the white matter lesions adjacent to the atrium of the right lateral ventricle is compatible with acute inflammation/demyelination."

The significance of the December 20, 2020 MRI is another point of disagreement between Dr. Wilson and Dr. Zucconi. They agree that the December 20, 2020 MRI shows demyelination in the area where a lesion was detected in 2017. Exhibit 45 at 6; Exhibit C at 7. Dr. Zucconi reasons that because Ms. Inyang developed a demyelinating lesion at this location in 2020, it is likely that the 2017 lesions was also demyelinating. Exhibit C at 7-8. In contrast, Dr. Wilson asserts that "new demyelinating injury in this location in 2020 does not imply that injury at the same location observed in 2017 is of demyelinating origin." Exhibit 45 at 6.

The remaining MRIs do not meaningfully contribute to determining whether Ms. Inyang suffered from NMOSD before her vaccination.

III. Standards for Adjudication[7]

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

Here, although the parties agree with the diagnosis of NMOSD, they dispute whether Ms. Inyang was suffering from NMOSD on the date of vaccination. Although Ms. Inyang was diagnosed as suffering from NMOSD after the vaccination, the date of diagnosis does not always determine the date of onset. See Rocha v. Sec'y of Health & Hum. Servs., No. 16-241V, 2024 WL 752787, at *33 (Fed. Cl. Spec. Mstr. Feb. 1, 2024) (stating "As a matter of logic, a doctor's detection of a disease does not establish the date the disease began" and citing appellate cases affirming findings regarding date of onset).

IV. Analysis

Preliminarily, basic areas of agreement should be set forth. The parties agree:

- Ms. Inyang suffered from NMOSD by December 6, 2017. Exhibit 45 at 7 (Dr. Wilson); Exhibit C at 8 (Dr. Zucconi).

[7] This Finding is being issued before the release of the transcript.

- Ms. Inyang's spinal MRIs from December 4, 2017 are consistent with NMOSD;

- Ms. Inyang's brain MRIs from December 2017 show chronic lesions that are of such age that they must have existed before the November 21, 2017 vaccination.[8]

Despite those agreements, Dr. Wilson and Dr. Zucconi disagree on a question critical to whether Ms. Inyang may establish that the flu vaccine caused her NMOSD. This critical question is whether the chronic lesions detected on the December 2017 MRIs are evidence of a demyelinating injury. A fact hearing was held on August 2, 2024 for the experts to testify about and annotate the MRI images.

As previously stated, both experts were credible, in part, because they did not exaggerate their knowledge. For example, Dr. Zucconi admitted that he could not say that Ms. Inyang suffered from NMO before her vaccination "definitively." Yet, he could say---and did say---that it was more likely than not that the lesions on the two brain MRIs from December 2017 were demyelinating. Dr. Wilson's opinion to the contrary does not prevent a finding of fact crediting Dr. Zucconi's opinion. See Doe 11 v. Sec'y of Health & Hum. Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010) (noting that conflicting evidence does not mean a special master's finding is arbitrary).

Dr. Zucconi's opinion that Ms. Inyang began suffering from NMOSD before the vaccination is credited for several reasons. First, the 2017 brain MRIs revealed lesions in four different areas of the brain. Dr. Wilson and Dr. Zucconi agreed that these four areas correspond to areas where AQP4 is highly expressed and, therefore, are common places for lesions in people with NMOSD. Dr. Wilson is not wrong, as a matter of theory, to say that people might develop infarcts in these same regions. However, it seems unlikely that all four lesions developed in areas with AQP4 expression without any being demyelinating. See W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1358 (Fed. Cir. 2013) (ruling that a special

[8] This agreement about the chronicity of the December 2017 brain lesions avoids any controversy over how long lesions enhance. For information about the duration of enhancement, see W.C. v. Sec'y of Health & Human Servs., No. 07-456V, 2011 WL 4537877, at *6-7 (Fed. Cl. Spec. Mstr. Feb. 22, 2011) (discussing Cotton article), mot. for rev. denied on relevant grounds, 100 Fed. Cl. 440, 451 (2011), aff'd, 704 F.3d 1352, 1359-60 (Fed. Cir. 2013).

master's crediting of one expert's testimony about chronicity of MRI was not arbitrary).

Next, the evolution of lesions is more consistent with a single disease process. Dr. Wilson and Dr. Zucconi agreed that the 2020 MRI revealed an acute demyelinating lesion in Ms. Inyang's left medulla. This location is also the location of a small lesion seen on the first MRI in December 2017 and faintly seen on the second MRI in December 2017. Dr. Zucconi reasons persuasively that it would seem unlikely for one person to have an infarct in one part of the brain and then develop demyelination in the same spot three years later. Dr. Wilson's alternative view---essentially that the similar location but different etiology was simply coincidental---is less persuasive.

Third, there is relatively little persuasive evidence that Ms. Inyang suffers from small vessel disease. In Dr. Zucconi's first report, he identified the ways small vessel disease typically appears on imaging. Exhibit C at 5, citing exhibit C-7 (Aowei Lv et al., "Dawson's Fingers in Cerebral Small Vessel Disease," 11 Front. Neurol. 669 (2020)). At the hearing, Dr. Wilson agreed that these features are typical. Dr. Zucconi also asserted that Ms. Inyang's MRIs did not reveal these features. Exhibit C at 5. Again, Dr. Wilson agreed.

Furthermore, no treating doctor appears to have diagnosed Ms. Inyang with small vessel disease.

The expert Ms. Inyang retained, Dr. Steinman, stated that Ms. Inyang "clearly" had "neuromyelitis optica." Exhibit 18 at 12. Dr. Steinman does not suggest that she also suffered from a small vessel disease. See id.

None of these factors is dispositive by itself. But, collectively, these factors preponderate in favor of a finding that Ms. Inyang suffered from an undiagnosed case of NMOSD before she was vaccinated on November 21, 2017.

Because Ms. Inyang suffered from NMOSD before the vaccination, she cannot claim that the flu vaccine caused her condition. Locane v. Sec'y of Health & Hum. Servs., 685 F.3d 1375, 1381 (Fed. Cir. 2012). Ms. Inyang, however, may continue with her claim that the flu vaccine significantly aggravated her NMOSD. A status conference will be held to discuss this topic.

V. Conclusion

The evidence preponderates in support of a finding that the chronic lesions on Ms. Inyang's brain MRIs from December 2017 were demyelinating.

The parties are directed to provide this order to any expert whom they retain.

A status conference is set, *sua sponte*, for **Wednesday, August 28, 2024 at 10:00 A.M.** Petitioner should be prepared to discuss potential next steps.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master